CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

Methyl Nonyl Ketone

Chemical Code # 000877, Tolerance # 50226
SB 950 # 282

May 13, 2002

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, no study on file
Chronic toxicity, dog:	Data gap, no study on file
Oncogenicity, rat:	Data gap, no study on file
Oncogenicity, mouse:	Data gap, no study on file
Reproduction, rat:	Data gap, no study on file
Teratology, rat:	Data gap, inadequate study, no adverse effect indicated
Teratology, rabbit:	Data gap, no study on file
Gene mutation:	No data gap, no adverse effect
Chromosome effects:	No data gap, no adverse effect
DNA damage:	No data gap, no adverse effect
Neurotoxicity:	Not required at this time

Toxicology one-liners are attached.

All record numbers through 128133 were examined.
** indicates an acceptable study.
Bold face indicates a possible adverse effect.

File name: T020513.
Prepared by H. Green and Gee, 5/13/02

Methyl nonyl ketone and related compounds are components of dog and cat repellants.

A 21-day dermal study is on file and has been reviewed as upgradeable.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

No study on file

CHRONIC TOXICITY, RAT

No study on file

CHRONIC TOXICITY, DOG

No study on file

ONCOGENICITY, RAT

No study on file

ONCOGENICITY, MOUSE

No study on file

REPRODUCTION, RAT

No study on file

TERATOLOGY, RAT

50226 - 001 920591 "Teratology study in Rats." (International Bio-Research, Inc., 1977) One page summary of 035960 in 50226 - 002. Reviewed by J. Wong, 6/28/85.

50226 - 002 035960 " Effect of "MGK Dog and Cat Repellant, Lot 6623" on the embryonic development of rats after oral applikation." (Sterner, W., Grahwit, G. and Chibanguza, G., International Bio-Research, Inc., January 1977) MGK Dog and Cat Repellant (lot 6623, no purity or description) was given to Wistar rats, 20/group, at 0 (peanut oil), 50, 200 or 800 µl/kg [possible 600µl/kg, unclear] on days 5 through 15 of gestation. The concentrations of the dosing material were 0.5, 2.0 or 8.0 [6.0]% (v/v) with 10 ml/kg by gavage. There were no effects on clinical signs or body weight. Food consumption was decreased and water intake increased in test groups with no dose response in food consumption. The mean fetal weights for males and females were statistically lower in the low dose group but not at the mid or high doses. There were total litter resorptions of 0, 1, 2 and 2 in control through high doses, respectively and although the mean resorptions

per doe were increased with dose, there was no statistical significance. There were no fetal findings upon visceral and skeletal examination. **No adverse effects**. **Unacceptable** (no characterization of the test article, no analyses of dosing material, no justification of dose selection, unclear high dose). Possibly upgradeable. (Gee, 5/8/02)

TERATOLOGY, RABBIT

No study on file

GENE MUTATION

** 50226 - 007 114212 "Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test)." (Richard H.C. San and J. Blair Shelton, Microbiological Associates, Inc., Rockville, MD., Report # T9487.501, 10 January 1991). Methyl nonyl ketone (lot 12036, 98%) was tested in a reversion assay by plate incorporation, plated in triplicate in a single trial, in the presence and absence of rat liver activation, using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 with 48-hour exposure at 0 (dimethylsulfoxide), 3.3, 10, 33, 100, 333, and 1000 *m*g/plate. **No increase in reversion frequency. Acceptable.** (H. Green and Gee, 5/7/02).

** 50226 - 007 114216 "L5178Y TK+/- Mouse Lymphoma Mutagenesis Assay." (Richard H. C. San and Jane J. Clarke, Microbiological Associates, Inc., Rockville, MD, Report # T9487.701, 11 December 1990). Methyl nonyl ketone (lot 12036, 98% purity) was assayed with mouse L5178Y lymphoma cells, 4-hour exposure, single culture per concentration, with and without Aroclor-induced male rat liver S9 activation. Concentrations were 0 (DMSO), 0.0032, 0.0042, 0.0056, 0.0075, 0.010, 0.013, 0.018, 0.024, 0.032, 0.042, 0.056, 0.075, 0.10, 0.13, 0.18, or 0.24 *m*l/ml. Following the expression period, triplicate plates were made for mutation frequency and an additional three plates for viability counts. Results were reported as the mean and standard deviation (no individual plate counts). Colonies were not sized at that time. **No increase in mutation frequency. Acceptable** with minor deficiencies (individual plate counts). (H. Green and Gee, 5/8/02).

CHROMOSOME EFFECTS

** 50226 - 007 114215 "Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells." (Donald L. Putman and Marcia J. Morris, Microbiological Associates, Inc., Rockville, MD, Report # T9487.337, 21 December 1990). Methyl nonyl ketone (lot 12036, 98%) was assayed for induction of chromosomal aberrations using Chinese Hamster ovary (CHO-K1) cells in duplicate cultures with rat liver S9 activation (2-hour treatment and14-hour harvest) and without activation (10-hour treatment and 12-hour harvest). Concentrations used were 0 (DMSO), 0.0065, 0.013, 0.025, 0.05, or 0.1 *m*l/ml. **No increase in chromosomal aberration frequency. Acceptable**, with no adverse effects. (H. Green and Gee, 5/8/02)

DNA DAMAGE

** 50226 - 007 114214 "Unscheduled DNA Synthesis in Rat Primary Hepatocytes." (Rodger D.

Curren, Microbiological Associates, Inc., Rockville, MD, Report # T9487.380, 15 January 1991). Methyl nonyl ketone (lot 12036, 98%) was tested in an unscheduled DNA synthesis assay by autoradiography with triplicate cultures of primary hepatocytes from an adult male Fischer 344 rat . Methyl nonyl ketone concentrations were 0 (DMSO), 0 (Williams' Medium E), 0.003, 0.01, 0.03, 0.1, 0.3, 0.6, and 1.0 µl/ml, with 18 to 20 hour exposure. Concentrations of 0.6 and 1.0 ul/ml were too toxic to score. **No increase in unscheduled DNA synthesis. Acceptable**, with no adverse effects. H. Green and Gee, 5/7/02)

NEUROTOXICITY

Not required at this time.

OTHERS

50266 - 007 114210 "Technical Bulletin: MGK® Dog and Cat Repellant" (McLaughlin Gormley King, 1/81). The document presents an overview of the repellant, physical/chemical properties and uses. No worksheet. (Gee, 5/7/02).

50225 - 005 065536 "Subacute Dermal Toxicity." (Wisconsin Alumni Foundation Laboratories, WARF # 5122135, 3/14/66) New Zealand White rabbits were tested with 1.0 or 2.0 ml/kg of the formulation X-1309-65 (not described) or 2 ml of isopropanol for the control group. There were 10/sex in the treated groups and 5/sex in controls. Exposure was for 8 hours, 5 days/week for three weeks. An occlusive patch was not mentioned in the report. Body weight and food consumption data were collected weekly and were similar. Hematology and urinalysis exams were conducted initially and at week three and were not remarkable. Limited tissues were examined for histology. Evidence of mild inflammatory cell infiltration was seen in the liver, lungs and kidney of control and test animals. The conclusion of the author was that the test article was non-toxic when applied dermally at the above doses. Unacceptable but upgradeable with the submission of a complete and legible conclusion section. (Adapted from J. Berliner, 2/19/88 by Gee, 5/8/02)

50226 - 011 " Methyl nonyl ketone 21 day dermal toxicity study in the rabbit." (Thomas, F. L. and R. F. A. Husband, Toxicol Laboratories Limited, Laboratory Project ID: MCA/20/C, January 4, 1994) Methyl nonyl ketone (lot 12036, 100%) was applied to the skin of New Zealand White rabbits, 5/sex/group, at 0 (corn oil), 30, 100 or 300 mg/kg/day in 2 ml/kg, 6 hours per day, 7 days per week, for 21 days. The treated site was covered with a semi-occlusive bandage. There were no conclusive treatment-related effects on body weight, food consumption, clinical signs, hematology or clinical chemistry. Urinalysis and ophthalmology were not included. Skin effects (erythema, edema, desquamation and pustule formation) were noted in all groups including the control with no apparent dose-relationship. The authors attributed the skin effects to the combination of corn oil and the semi-occlusive dressing. There were no histological findings. Systemic NOEL = 300 mg/kg/day. No adverse effects. **Unacceptable** (dose selection was not justified), upgradeable. (Gee, 5/10/02)